Absorb Bioresorbable Scaffold Versus Xience Metallic Stent for Prevention of Restenosis Following Percutaneous Coronary Intervention in Patients at High Risk of Restenosis: rationale and design of the COMPARE ABSORB trial

Chun Chin Chang, MD; Yoshinobu Onuma, MD, PhD; Stephan Achenbach, MD, PhD; Emanuele Barbato, MD, PhD; Bernard Chevalier, MD; Stéphane Cook, MD; Dariusz Dudek, MD, PhD; Javier Escaned, MD, PhD; Tommaso Gori, MD, PhD; Viktor Kočka, MD, PhD, Giuseppe Tarantini, MD, PhD, Nick E.J. West, MD, Marie-Claude Morice, MD, Jan G.P. Tijssen, PhD, Robert-Jan van Geuns, MD, PhD; Pieter C. Smits, MD, PhD; on behalf of the COMPARE ABSORB trial investigators

Supplementary data

I. Sample size calculation

Primary hypothesis I

- Non-inferiority in TLF (CVD/MI/TLR) at 1 year
- TLF in Xience EES is 8.5%
- Non-inferiority margin is 4.5%
- Alpha = 0.05
- Power = 90%
- Required sample size: 808 x 2 = 1616 pts

Primary Hypothesis II

- Superiority after 3-year landmark
- Expected TLF rate after 3 years with Xience EES is 11.1%
- Relative risk ratio from 3 to 7 years of Absorb BVS against Xience EES = 0.60
- Expected TLF rate with Absorb BVS is 6.64%
- Attrition rate 0.9%/ year
- Sample size = 2100
- Statistical power = 90.3%
- The trial still has 80% power even if relative risk ratio from 3 to 7 years of Absorb BVS against Xience EES is 0.65.

Additional Hypothesis

- Cumulative superiority in TLF at 7 years
- Expected TLF rate with Xience EES at 7 year is 22.9%
- Absorb BVS reduces TLF at 7 years to 19.1% (relative risk ratio from 3 to 7 years of Absorb BVS against Xience EES is 0.60)
- With 2 x 1004 pts, the study has approximately 55% power of showing superiority of Absorb BVS over Xience EES within 7 years (α=0.05, two sided).

Secondary Hypothesis

- Using the data of ABSORB II trial, the cumulative incidence of angina endpoint at one year in the Xience EES arm is assumed to be 25%. With 2 x 1050 patients, the study has a 90% power to statistically detect a decrease to 19.1% in the Absorb BVS arm.

II. Study Organization

Principal investigator
Pieter C. Smits

Co-Principal investigator
Robert-Jan van Geuns

Executive Committee
Pieter C. Smits
Robert-Jan van Geuns
Marie-Claude Morice
Yoshinobu Onuma

Steering Committee members
Pieter C. Smits
Robert-Jan van Geuns
Jan Tijssen
Viktor Kočka
Dariusz Dudek
Bernard Chevalier
Tommaso Gori
Stephan Achenbach
Giuseppe Tarantini
Emanuele Barbato
Nick West
Javier Escaned
Marie-Claude Morice
Yoshinobu Onuma

Data Safety Monitoring Board (DSMB)
Stefan James
Eric Boersma
Michel Bertrand

Safety Reporting
The CRO CERC (7 rue du Théâtre, 91300 Massy, France) is responsible for entering all Serious Adverse Events (SAEs) including the assessment regarding relationship to the device (SADEs) or to the procedure from the eCRF in a safety database and for reporting these SAEs and SADEs according to the MEDDEV 2.7/3 guidelines and national requirements.

Data Management, Site Management and Monitoring
Data management, site management and monitoring will be conducted by the Clinical Research Organisation (CRO) CERC (7, rue du theatre, 91300 Massy, France).

Core Laboratories
The independent QCA and IVUS Core Lab at Cardialysis (Cardialysis B.V., PO Box 2125, 3000 CC Rotterdam, The Netherlands) will analyze angiograms obtained during and/or

before procedure. Members of the Angiographic/IVUS Core Lab are not involved as investigators or co-investigators in this study.

Statistical Analysis

The Cardialysis (Cardialysis B.V., PO Box 2125, 3000 CC Rotterdam, The Netherlands) is responsible for the statistical analysis.